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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,544	01/19/2007	Eugene B. Chang	27373/40386	6616

4743 7590 08/02/2007
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EXAMINER

MI, QIUWEN

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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08/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,544	Applicant(s) CHANG ET AL.	
	Examiner Qiuwen Mi	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 13-27, 40, 41 and 43-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 28-39 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-12, 28-39, and 42 in the reply filed on 6/27/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-27, 40, 41, 43-48 are withdrawn from further consideration as being drawn to nonelected inventions.

Claims Pending

Claims 1-48 are pending. Claims 13-27, 40, 41, 43-48 are withdrawn as directed toward non-elected inventions. Claims 1-12, 28-39, and 42 are examined on the merits.

Claim Rejection 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 28-39, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated anti-inflammatory, cytoprotective compound.

To provide adequate written description and evidence of possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics of the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the invention only provides the description of an extract from a medium, and no description regarding the isolation procedure of any particular compound is being disclosed in the specification. It is not clear exactly what isolated compound Applicant is referring to, and there is no chemical name or structure being disclosed in the specification. Accordingly, in the absence of sufficient recitation of the compound with the corresponding structure and functional activity, the specification does not provide adequate written description of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed. The specification does not “clearly allow persons of ordinary skill in

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the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed compound being claimed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the compound. Adequate written description requires more than a mere statement of the total amount of the plant material being used. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention.

Claims 1-12, 28-39, and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an extract from a medium, does not reasonably provide enablement for an isolated compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

It is well known in the art that many thousands of natural compounds have been isolated from microorganism, and each product obtained from an extraction from a living microorganism is unpredictable in nature. As mentioned above, the invention only provides the description of an extract from a medium, and no description regarding the isolation procedure of any particular compound is being disclosed in the specification. It is the opinion of the Examiner, in light of the grave unpredictability in the art with regard to isolate each single compound from an extract of a living microorganism, elucidate each structure of the compound, and co-relate each compound with claimed functional activity, that Applicant is not enabled for an isolated compound as Instantly claimed. Even the most skilled of artisans would need to quantify each product for constituents as well as medicinal efficacy. Considering this evidence, the skilled artisan, lacking information with regard to any isolation procedure of a particular compound which will produce the instantly claimed anti-inflammatory compound, would necessarily need to perform tedious trial and error protocols without expectation of success in order to ascertain what compound would provide for the specific therapeutic uses as described in the specification.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; *however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35*

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U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 12 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the" in "the probiotic-conditioned medium". There is insufficient antecedent basis for this limitation in the claim.

Claim 2 recites the limitation "wherein the compound is present in an ether-extracted fraction of the probiotic-conditioned medium". Since claim 1 recites "an isolated...compound", and claim 2, depending upon claim 1, could not possibly still have an isolated compound being "present in an ether-extracted fraction".

Claims 12 and 39 contain the trademark/trade name VSL#3. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. Applicant is required to provide full generic names of the reagents that are used in the claims since VSL#3 does not tell one of ordinary skills in the art exactly what is in the compounds and such trademark can change the compositions at any time.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 12, 28, 29, 30, and 39 are rejected under 35 USC § 102 (e) as being anticipated by Versalovic et al. (US 2004/0208863) as evidenced by JP 2000236873 and Hamburger (US 1,459,359)*.

Versalovic et al. disclose an invention comprising a compound secreted from lactic acid bacteria that comprises anti-inflammation activity [0050]. Versalovic et al. also teach that *Lactobacillus* and other lactic acid bacterial species have been used in probiotic strategies for gastrointestinal infections and inflammatory bowel disease [0052]. Further more, Versalovic et al. indicate that administration of a mixture of *Lactobacillus* and *Bifidobacterium* sp. (VSL#3) in ulcerative colitis patients following colectomy has reduced recurrence of flare-ups in chronic proctitis (thus has cytoprotective effect) [0135]. Versalovic et al. also teach the pharmaceutical composition [0091] comprising pharmaceutically acceptable carrier or excipient [0092]. Since lactic acid bacterial species inherently secrete lactic acid (an organic acid), and as evidenced by JP 2000236873, lactic acid can be used as an anti-inflammatory agent, thus claim 3 is met. As further evidenced by Hamburger (US 1,459,395), ether is a suitable solvent for extracting lactic

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acid (page 1, right column, lines 65-70), therefore, lactic acid will be present in an ether-extracted fraction of the probiotic-conditioned medium, thus claim 2 is met.

Applicant is requested to note that it is regarded that "intended use" of a composition or product will not further limit claims drawn to a composition or product. See, e.g., *Ex Parte Masham*, 2 USPQ2d 1647 (1987) and *In Re Hack* 114, USPQ 161. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-3, 12, 28, 29, 30, and 39 are rejected under 35 USC § 102 (e) as being anticipated by Raz et al. (US 2005/0180962) as evidenced by JP 2000236873 and Hamburger (US 1,459,359)*.

Raz et al. disclose treating gastrointestinal inflammation (thus has cytoprotective effect) using a formulation comprising inactivated probiotic bacteria VSL-3 [0202] and a pharmaceutically acceptable excipient [0010]. Raz et al. also teach that the composition must be compatible with maintaining viability of the lactic acid-producing microorganism [0074]. Since lactic acid bacterial species inherently secrete lactic acid (an organic acid), and as evidenced by

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JP 2000236873, lactic acid can be used as an anti-inflammatory agent, thus claim 3 is met. As further evidenced by Hamburger (US 1,459,395), ether is a suitable solvent for extracting lactic acid (page 1, right column, lines 65-70), therefore, lactic acid will be present in an ether-extracted fraction of the probiotic-conditioned medium, thus claim 2 is met.

Applicant is requested to note that it is regarded that "intended use" of a composition or product will not further limit claims drawn to a composition or product. See, e.g., *Ex Parte Masham*, 2 USPQ2d 1647 (1987) and *In Re Hack* 114, USPQ 161. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Therefore, the reference is deemed to anticipate the instant claim above.

* These references are merely cited in order to relay inherent properties, and are not used in the basis for rejection *per se*.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/
Patricia Leith
Primary Examiner
Art Unit 1655